DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

I-010969- X-0034-CE

AUG 07 2009

U.S. Fish & Wildlife Service
Aquatic Animal Drug Approval Partnership Program
Attention: David Erdahl, Ph.D.
Branch Chief, AADAP
4050 Bridger Canyon Road
Bozeman, MT 059715

Re: Claim for a categorical exclusion for investigational use of REWARD (diquat dibromide)

Dear Dr. Erdahl:

Your claim for a categorical exclusion dated April 29, 2009 does not meet the criteria for a categorical exclusion (CE) from the requirement to prepare an environmental assessment (EA) or an environmental impact statement (EIS). Your claim for CE was for the investigational use of REWARD (diquat dibromide) using a "repetitive treatment" regimen at four fish hatcheries in Iowa and Illinois. The drug is proposed for use in finfish to control mortality caused by bacterial gill disease and external flavobacteriosis. We note that your submission also included a request for an amended authorization. Please note that this letter only acknowledges your claim for a categorical exclusion. Your request for an amended authorization will be addressed in a separate letter (D-0032). In the future, please submit only one request per letter.

Your claim for a CE does not meet the criteria for exclusion because the proposed investigational use of REWARD may potentially result in extraordinary circumstances. Based on the available toxicity information for diquat dibromide, the potential for extraordinary circumstances to exist at facilities using a "repetitive treatment" regimen for REWARD cannot be ruled out. Additional information on a facility-by-facility basis is needed to determine if 1) either an environmental assessment is needed or 2) use limitations or other risk mitigation measures are needed in order to grant a categorical exclusion covering "repetitive treatment" of diquat dibromide in investigational studies. Completed Discharge Worksheets for the four facilities listed in your request should be submitted if available for prior years. In addition, at a minimum, for each of the four facilities you should submit following information: 1) the duration and concentration of treatment, 2) the size, type and number of units (e.g., tanks, raceway, ponds) in which treatment will occur, 3) the percentage of water volume in the entire facility that will be treated with diquat dibromide on a daily basis (average and maximum), 4) the expected amount of effluent dilution in receiving water (i.e., average water flow of effluent versus average water flow of receiving

water), and 5) a description of the effluent receiving water (e.g., river, lake) and its designated use(s), if any.

We remind you that normally you must submit either a claim for CE or an EA before you can ship investigational new animal drugs for use in clinical studies (21 CFR 511.1(b)(10)); however, the existing categorical exclusion for investigations under your INAD continues to apply for those facilities that are not using a "repetitive treatment" regimen for REWARD.

If you submit correspondence relating to this letter, your correspondence should reference the date and the principal submission identifier found at the top of this letter. If you have any questions or comments, please contact me at (240) 276-8177. You may also contact Charles Eirkson, at (240) 276-8173.

Sincerely,

Donald A. Prater, DVM
Director, Division of Scientific Support
Office of New Animal Drug Evaluation
Center for Veterinary Medicine